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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,075	05/15/2001	W. James Cook	06286-089002	5251

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EXAMINER
SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/858,075	COOK ET AL.	
	Examiner	Art Unit	
	Jehanne E Souaya	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *16 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *42,43,47 and 48* is/are allowed.

6)☒ Claim(s) *44-46 and 49-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5/2001* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

Enablement

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 44-45, and 49-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising the sequence of SEQ ID NO 2 and an isolated polypeptide encoded by a nucleic acid molecule comprising SEQ ID NO 1 or 3, or degenerate variants thereof, does not reasonably provide enablement for an isolated polypeptide that is encoded by a nucleic acid molecule at least 95% identical to SEQ ID NOS 1 or 3, an isolated polypeptide encoded by a nucleic acid molecule that specifically hybridizes at 68 deg C in 5x SSC/5x Denhardt's solution/ 1.0% SDS to SEQ ID NO 1 or SEQ ID NO 3, or isolated NMT polypeptides which are 65%, 75%, 85%, 95%, 98% identical to SEQ ID NO 2, or such polypeptides with conservative amino acid substitutions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claimed recitation of hybridization conditions and % identity broadly encompass variants, mutants, and homologs, from any source, of SEQ ID NO 2. However, the specification does not enable these variants, homologs, and mutant NMT from any source because there is insufficient guidance and description teaching how to make all of these embodiments. The specification teaches the nucleotide (SEQ ID NOS 1 and 3) and deduced amino acid (SEQ ID NO 2) sequences of Aspergillus fumigatus NMT. However, neither the specification nor the art teach variants of Aspergillus fumigatus NMT. Accordingly, neither the art nor the specification provide teaching or guidance for the skilled artisan to determine whether a specific polypeptide sequence would fall within the scope of the claims, such as "polypeptides encoded by a nucleic acid molecule that specifically hybridizes at 68 deg C in 5x SSC/5x Denhardt's solution/ 1.0% SDS to SEQ ID NO 1 or SEQ ID NO 3", or "isolated NMT polypeptides" which are 65%, 75%, 85%, 95%, 98% identical to SEQ ID NO 2, or such polypeptides with conservative amino acid substitutions. The claims encompass polypeptides with as little as one amino acid change from SEQ ID NO 2, however, it is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. For example, Rajala et al (Biochemical and Biophysical Research Communications, vol. 288, pp 233-239, 2001) teach that a conservative substitution of phenylalanine for tyrosine at position 100 of human NMT served NMT as a poor substrate for Lyn kinase (see abstract), and that substitution at positions 37, 70, and 93 reduces the ability of Lyn to phosphorylates NMT by more than half.

Therefore, neither the specification nor the art enable the skilled artisan to make or use the claimed invention without undue experimentation. The claims are drawn to nucleotide sequences that are unknown and it would require trial and error analysis for the skilled artisan to screen every potential variant, mutant, or homologue polypeptide sequence to determine the effect on the function of Aspergillus fumigatus NMT. Such analysis is clearly unpredictable due to the lack of guidance from the specification as to which amino acids could be altered, either conservatively or not, and provide either a mutant or fully functional polypeptide, and the teachings of unpredictability with regard to even a single conservative amino acid change, as taught by Rajala et al, and therefore considered undue.

Written Description

4. Claims 44-46 and 49-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed recitation of hybridization conditions and % identity broadly encompass variants, mutants, and homologs, from any source, of SEQ ID NO 2. However, the specification does not teach or describe this large genus of variants, homologs, and mutant NMT from any source because there is insufficient guidance and description teaching how to make all of these embodiments. The specification teaches the nucleotide (SEQ ID NOS 1 and 3) and deduced amino acid (SEQ ID NO 2) sequences of Aspergillus fumigatus NMT. However, neither the

specification nor the art teach variants, mutants or homologs of Aspergillus fumigatus NMT. Further, the specification does not teach which amino acids of SEQ ID NO 2 could be altered to result in a protein with the same function as SEQ ID NO 2. Further, the specification does not teach or describe which amino acids could be altered to result in a protein with altered activity as compared to SEQ ID NO 2, or what that altered activity would be. With regard to the recitation of "NMT polypeptide" or "N myristoyl transferase polypeptide", such is not considered limited to only fully functional NMT polypeptides. Accordingly, the recitation of a single protein of SEQ ID NO 2 does not provide a substantial portion of the claimed genus of mutants, variants, and homologs of SEQ ID NO 2, from any source.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NOS: 2 and polypeptides encoded by the nucleic acid of SEQ ID NO 1 or 3, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims

directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

With regard to claim 46, it is noted that the claim is drawn to a polypeptide encoded by a nucleic acid sequence contained within the ATCC and recites an ATCC accession number. Deposit of the nucleic acid sequence must be perfected to overcome the written description requirement. While such was perfected in a declaration in the parent application 09/163,444, declarations do not carry over from one application to another. The rejection with respect to claim 46 can be overcome by filing a declaration to perfect the deposit (see MPEP chapter 2400).

Indefinite

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 50-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 50-53 are indefinite over the phrase "at least about" because the metes and bounds of the invention are not clear. As the CAFC noted, and affirmed, regarding the district court determination of this phrase in Amgen Inc. v. Chugai Pharmaceutical Co. Ltd. (CA FC) 18 USPQ2d 1016 at page 1031 "the court held the "at least about" claims to be invalid for indefiniteness." Here too, the situation is that there is close prior art, applied as a 102(b) for a lower limit value, and the claim is indefinite with regard to the values encompassed.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 45, 49, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Lodge et al (Journal of Biological Chemistry, vol. 269, pp 2996-3009; 1994).

Lodge et al teach an NMT polypeptide sequence from Histoplasma capsulatum which has 72.4% identity to SEQ ID NO 2 (encompasses "at least about 75%" as it is unclear how much lower than 75% the lower limit of "about" is; alignment provided). The nucleic acid encoding such polypeptide has regions of complementarity to SEQ ID NO 3 (alignment provided) and would be expected to hybridize to SEQ ID NO 3.

Conclusion

9. Claims 42, 43, 47, and 48 are free of the cited prior art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Jehanne Souaya
Patent examiner
Art Unit 1634
June 19, 2003